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PAUL D. BIANCO Fleit Gibbons Gutman Bongini & Bianco PL 21355 EAST DIXIE HIGHWAY SUITE 115 MIAMI, FL 33180			EXAMINER TYSON, MELANIE RUANO	
			ART UNIT	PAPER NUMBER
			3773	
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			03/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,401

Applicant(s)

BONUTTI, PETER M.

Examiner

MELANIE TYSON

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 16-19, 24 and 26-61 is/are pending in the application.
- 4a) Of the above claim(s) 26-31, 45, 51-53, 60 and 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 16-19, 24, 32-44, 46-50, and 54-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-544)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to the applicant's amendment received 22 December 2009. The amendments made to the claims do not place the application in condition for allowance for the reasons set forth below. Claims 8-15, 20-23, and 25 remain cancelled. Claims 26-31, 45, and 51-53 remain withdrawn from consideration. New claims 58-61 have been added.

Response to Arguments

Applicant's arguments with respect to the rejoinder of claims 26-31, 45, and 51-53 have been fully considered but they are not persuasive. The applicant argues elected species III includes the embodiment recited in claims 26-31, 45, and 51-53. However, it is the examiner's position that Figures 9-15 fail to illustrate a carrier on a body having a magnetic element, wherein the carrier is a slot, eyelet, or barb. Such an embodiment is illustrated in species I or II (Figures 1-3 or 4-8) and described in corresponding paragraphs 47-49. Therefore, claims 26-31, 45, and 51-53 remain withdrawn from consideration. The amendments made to claims 54, 16, and 18, enable claims 16 and 18 to now read on the elected species. Therefore, claims 16 and 18 are no longer considered withdrawn and have also been examined. Finally, new claims 60 and 61 are drawn to a non-elected species. Specifically, nowhere does the applicant describe in paragraphs 53-64 or illustrate in Figures 9-15 that the medical implant (suture) may have a magnetic component. The embodiment in which the medical implant includes a magnetic component is illustrated in species I. Therefore, claims 60

and 61 are withdrawn from further consideration as being drawn to a non-elected species.

Applicant's arguments with respect to claims 1-7, 16-19, 24, 32-44, 46-50, 54-59 and the prior art have been considered but are moot in view of the new ground(s) of rejection.

Specification

The disclosure is objected to because of the following informalities: the first line of the specification is missing the Patent No. of the parent case. Appropriate correction is required.

Claim Objections

Claim 24 is objected to because of the following informalities: amended claim 24 recites the position of the electromagnet with respect to tissue. Since the claim is an apparatus claim and thus such language is intended to be functional language, language such as --configured to-- or --adapted to-- should be utilized such that the claim reads "wherein the electromagnet is configured to be positioned adjacent to the tissue." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 16-19, 24, 32-44, 46-50, and 54-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description

requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. At the time the application was filed, the applicant failed to disclose the combination of a magnetizable material disposed in at least on of the members and an electromagnet disposed in at least one of the members. The applicant disclosed a magnetizable material disposed in one member and an electromagnet in the other member. However, the applicant failed to disclose an embodiment in which, for example, both members having magnetizable material and an electromagnet (or multiple electromagnets). Therefore, such an amendment is considered new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 17, 19, 41, 44, 47, and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, from which claim 3 depends, requires an electromagnet be disposed in at least one of the tissue engaging members. Claim 3 has been amended to require the first and second tissue engaging members being electromagnets. This language is confusing, since claim 1 requires the electromagnets are disposed in the members and thus claim 3 would require an electromagnet disposed within an electromagnet. Claims 17 and 19 require the medical implant to be a needle. This language is confusing since it is the suture that is implanted with the needle merely being an implement for driving the

suture through tissue. This language indicates the needle is implanted into tissue which is confusing. Claim 41 recites the limitation "said magnetic field generator." There is insufficient antecedent basis for this limitation in the claims. Claims 44 and 55 recite the limitation "the medical implant." There is insufficient antecedent basis for this limitation in the claims. Amended claim 47 requires both the first and second tissue engaging members include electromagnets. This language is confusing since, claim 1, from which claim 47 depends, already requires at least one member having an electromagnet and at least one member having magnetizable material (which is disclosed as including an electromagnet).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 6, 24, 32, 33, 34, 37, 39, 40-42, 44, 46-50, 55, 57, and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Francischelli (U.S. Patent No. 6,699,240 B2).

Francischelli discloses an apparatus capable of moving a portion of tissue having two tissue sections (see entire document) comprising a first and second tissue engaging members (jaws 16 and 18) movable relative to each other capable of releasably holding

a medical implant, a pivot connecting the first and second tissue engaging members (for example, see Figure 1), a magnetizable material and electromagnet each being disposed in at least one tissue engaging member, wherein the magnetizable material may also be an electromagnet (for example, see column 2, lines 8-16), a biasing member (first and second handles 12 and 14) to spread (open) and to mechanically urge or compress the tissue engaging members, and the distal tips of the jaw may hold an implant and thus may be considered a "holder" as recited in the claims, wherein generation of a magnetic field would move the tissue engaging members as recited in the claims, the magnetizable material does not dissolve or absorb within the body and thus is considered "permanent" as recited in the claims, the strength of electromagnets are variable, the polarity of electromagnets are reversible and thus may attract or repel each other, the tissue engaging members with the electromagnets may be positioned anywhere along or surrounding the tissue and thus are considered to be "selectably" positionable or "alterable" adjacent tissue, and electromagnets are selectively activatable and deactivatable. With further respect to claim 6, Francischelli inherently discloses a control to control the electromagnet in that a current must be supplied to an electromagnet in order for it to work.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Francischelli. Francischelli discloses the claimed invention except for the magnetizable material being iron. However, iron is a well known magnetizable material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the magnetizable material of iron, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Francischelli as applied to claim 40 above, in view of Wilkinson (U.S. Patent No. 3,577,991). Francischelli discloses the claimed invention except for a separate biasing member for spreading the tissue engaging surfaces. Wilkinson discloses an apparatus comprising tissue engaging surfaces (13 and 14) and handles (10 and 11) for compressing the tissue engaging surfaces. Wilkinson teaches a biasing member (15) for holding the tissue engaging surfaces in an open configuration (for example, see column 2, lines 1-4). Thus, it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Wilkinson to the device of Francischelli

would have yielded predictable results and resulted in an improved system, namely, a system that would automatically bias the tissue engaging surfaces open, thus enabling a user to operate the tissue engaging surfaces with only a single input to the handles (i.e., compressing the handles together closes the tissue engaging surfaces and releasing the handles automatically spreads the tissue engaging surfaces open).

Claims 4, 7, 16-19, 35, 36, 54, 56, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda et al. (U.S. Patent No. 5,824,009) and Francischelli.

Fukuda discloses an apparatus for moving tissue or an implant through tissue (see entire document) comprising a first tissue engaging member (1) being configured to releasably hold a medical implant (a suture 3b, which is attached to a needle), a second tissue engaging member (2) being movable relative to the first engaging member (the surfaces are both movable relative to each other) in order to contact a second tissue and to penetrate the medical implant into the tissue, a pivot connecting the first and second tissue engaging members (for example, see Figure 1), a biasing member (first and second handles 7, 7) to spread (open) and to mechanically urge or compress the tissue engaging surfaces, and a holder (4). Fukuda fails to disclose a magnetizable material and an electromagnet each in at least one of the tissue engaging members.

Francischelli discloses an apparatus capable of moving a portion of tissue having two tissue sections (see entire document) comprising a first and second tissue engaging members (jaws 16 and 18) movable relative to each other. Francischelli teaches a

magnetizable material and electromagnet each being disposed in at least one tissue engaging member, wherein the magnetizable material may also be an electromagnet (for example, see column 2, lines 8-16), wherein generation of a magnetic field would move the tissue engaging members as recited in the claims, the magnetizable material does not dissolve or absorb within the body and thus is considered "permanent" as recited in the claims, the strength of electromagnets are variable, the polarity of electromagnets are reversible and thus may attract or repel each other, the tissue engaging members with the electromagnets may be positioned anywhere along or surrounding the tissue and thus are considered to be "selectably" positionable or "alterable" adjacent tissue, and electromagnets are selectively activatable and deactivatable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate magnets in Fukuda's tissue engaging members as taught by Francischelli. Doing so would enhance compression between the tissue engaging members (for example, see column 2, lines 4-7), thus reducing the risk of the tissue slipping out from between the tissue engaging members while the medical implant is driven through tissue.

With further respect to claim 16, it is well known to form sutures from bio-resorbable materials. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form Fukuda's suture from a bio-resorbable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 16-19, 24, 32-36, 38, 44, 49, 50, 54, 55, and 58 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-26 of U.S. Patent No. 6,719,765 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-7, 16-19, 24, 32-36, 38, 44, 49, 50, 54, 55, and 58 of the examined application are generic to the device recited in claims 11-26 of the '765 patent. That is, claims 11-26 of the '765 patent fall entirely within the scope of claims 1-7, 16-19, 24, 32-36, 38, 44, 49, 50, 54, 55, and 58 of the examined application, or, in other words, claims 1-7, 16-19, 24, 32-36, 38, 44, 49, 50, 54, 55, and 58 of the examined application are anticipated by claims 11-26 of the '765 patent. Specifically, since a suture passer is a

species of the generic category defined by "an apparatus for moving a medical implement," the device of claims 1-7, 16-19, 24, 32-36, 38, 44, 49, 50, 54, 55, and 58 are anticipated by claims 11-26 of the '765 patent reciting "a suture passer."

Claim 38 would have been obvious over the '765 patent claims. Specifically, iron is a well know magnetizable material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide iron as the magnetizable material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 37, 39-43, 46, 49, 50, 56, 57, and 59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-26 of U.S. Patent No. 6,719,765 B2 in view of U.S. Patent No. 3,577,991 (Wilkinson). Here, claims 11-26 of U.S. Patent No. 6,719,765 B2 recites a device for inserting a suture through tissue comprising electromagnets. The device of claims 11-26 differ from claims 37, 39-43, 46, 49, 50, 56, 57, and 59 herein in that it fails to disclose the presence of a pivot connecting the handles and a biasing member for spreading the tissue engaging surfaces. However, Wilkinson discloses an apparatus for moving an implement comprising tissue engaging surfaces (13 and 14) and handles (10 and 11) for compressing the tissue engaging surfaces. Wilkinson teaches a pivot (12) connecting the handles in order to operate the tissue engaging surfaces and a biasing member (15) for holding the tissue engaging surfaces in an open configuration (for example, see column 2, lines 1-4). Thus, it would have been recognized by one of

ordinary skill in the art that applying the known technique taught by Wilkinson to the device of the '765 patent claims would have yielded predictable results and resulted in an improved system, namely, an operable system that would automatically bias the tissue engaging surfaces open, thus enabling a user to operate the tissue engaging surfaces with only a single input to the handles (i.e., compressing the handles together closes the tissue engaging surfaces and releasing the handles automatically spreads the tissue engaging surfaces open).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MELANIE TYSON** whose telephone number is

(571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./
Examiner, Art Unit 3773
March 15, 2010

/(Jackie) Tan-Uyen T. Ho/
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